

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
EL PASO DIVISION

ORIGINAL

ALICIA SEPULVEDA,
INDIVIDUALLY AND AS
PERSONAL REPRESENTATIVE
OF THE HEIRS OF AND ESTATE
OF BRAULIO SEPULVEDA,
DECEASED, AND NORMA ALICIA
POSADA, RACHEL MORRIS,
ELIZABETH STEPHENSON AND
RUTH ALLEN, INDIVIDUALLY,
Plaintiffs,

vs.

SMITHKLINE BEECHAM
CORPORATION
d/b/a GLAXOSMITHKLINE,
Defendant.

JUDGE DAVID BRIONES

CIVIL ACTION NO. _____

EP08CA00006

JAN 07 2008

CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY Fm DEPUTY CLERK

PLAINTIFFS' ORIGINAL COMPLAINT

COMES NOW Alicia Sepulveda, Individually and as Personal Representative of the Heirs and Estate of Braulio Sepulveda, Deceased (Decedent) and Norma Alicia Posada, Rachel Morris, Elizabeth Stephenson and Ruth Allen, Individually (Plaintiffs), by their attorneys, THE DRINNON LAW FIRM, PLLC and for cause of action against Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and state as follows:

I. INTRODUCTION AND PARTIES

This is a civil action brought by Plaintiffs for damages arising out of their Decedent's ingestion of Rosiglitazone, which was manufactured, distributed and sold to the Decedent by Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE.

1.01 Alicia Sepulveda is the surviving spouse to Braulio Sepulveda, now deceased. Plaintiffs Norma Alicia Sepulveda, Rachel Morris, Elizabeth Stephenson and Ruth Allen are the only children of the Decedent.

1.02 Alicia Sepulveda is a citizen of the State of Texas who currently resides in El Paso County, Texas. As the surviving spouse of Braulio Sepulveda, Deceased, Mrs. Sepulveda has standing to bring a suit for damages due to the wrongful death of her husband. TEX. CIV. PRAC. & REM. CODE § 71.004 (Texas Wrongful Death Act). Mr. Sepulveda also has standing to bring a personal injury action on behalf of Decedent pursuant to TEX. CIV. PRAC. & REM. CODE § 71.021 (Texas Survival Act), which provides that "a personal injury action survives to and in favor of the heirs, legal representatives, and estate of the injured person." By agreement of the lawful heirs, Mrs. Sepulveda meets the requirement to bring this suit because: (1) Braulio Sepulveda died intestate; (2) the rightful heirs include Alicia Sepulveda, Norma Alicia Sepulveda, Rachel Morris, Elizabeth Stephenson and Ruth Allen; (3) there are no other living heirs, (4) no estate has been opened, and (5) no administration is necessary pursuant to Texas Probate Code § 178(b). *Ford Motor Company v. Cammack*, 999 S.W.2d (Tex.App. - Houston [14th Dist.] 1999).

Norma Alicia Sepulveda, Rachel Morris, Elizabeth Stephenson and Ruth Allen are the only surviving children of Braulio Sepulveda, Deceased. They have standing to bring a suit for damages due to the wrongful death of their father. TEX. CIV. PRAC. & REM. CODE § 71.004 (Texas Wrongful Death Act).

1.03 At all times relevant herein, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE (hereinafter collectively referred to as "GLAXO" or "Defendant"), was and is a British corporation with its principal place of business in the United States at One Franklin Plaza, Philadelphia, Pennsylvania 19101. GLAXO was and is in the business of profiting from the design, manufacture, marketing, distribution, and/or sales of the prescription drug Rosiglitazone under the brand names Avandia, Avandamet and Avandaryl.

II. JURISDICTION AND VENUE

2.01 This Court has subject matter jurisdiction over this lawsuit pursuant to the provisions of 28 U.S.C. § 1332. The parties to this lawsuit are citizens of different states and the matter in controversy exceeds the sum of \$75,000.00, exclusive of interest and cost. The Court has in personam jurisdiction over Defendant GLAXO, because it has done and continues to do business in Texas, has committed a tort, in whole or in part, in Texas and has continuing contacts in Texas. The exercise of jurisdiction over Defendant GLAXO will not offend traditional notions of fair play and substantial justice. Moreover, this Court has jurisdiction over this non-resident Defendant because Defendant has done business in the State of Texas, has marketed and sold its drugs in the State of Texas, and has continuing and systematic contacts within the State of Texas.

2.02 Pursuant to 28 U.S.C. § 1391(b), personal jurisdiction and venue are proper for this Defendant because Defendant transacts business in this District and therefore is deemed to reside in this District within this State/Venue. At all relevant times and concurrently hereto, Defendant has continuously conducted business in the Western District of Texas and this particular venue by marketing, distributing and selling its drug, Rosiglitazone. Moreover, Plaintiffs' Decedent was treated with Rosiglitazone in El Paso County, Texas which lies within the Western District of Texas.

III. CONDITIONS PRECEDENT

3.01. All conditions precedent has been performed or have occurred. FED. R. CIV. PROC. 9(c).

IV. FACTUAL BACKGROUND

4.01 In January 1997, the FDA was persuaded to approve the drug Rezulin to treat type two diabetes. Rezulin was the first approved glitazone class of drug. This class of drug was promoted to the diabetic patient population as able to assist the body in using insulin more effectively.

4.02 GLAXO proved to be not far behind in convincing the FDA to approve its own glitazone class drug for diabetic patients. The FDA agreed to GLAXO's request to approve GLAXO's Rosiglitazone (brand name "Avandia") in May, 1999. Such approval coincided closely thereafter with a marketing assault by GLAXO to seize its share of the huge market of diabetes suffering patients.

4.03 Within a few short years, it became evident that GLAXO's marketing and distribution strategy were nothing short of spectacular. Not only was Rosiglitazone

sold singularly as Avandia, but it was also mixed with metformin and sold as Avandamet.

4.04 Apparently, the phenomenal profits that GLAXO accumulated between May of 1999 through the summer of 2005 were not enough. At least by September, 2005 GLAXO was in possession of evidence that could reasonably be expected to diminish the sales of its second largest selling drug, Rosiglitazone. The evidence in its possession at the time was an overview analysis of approximately 42 different studies of patients using its drug, Rosiglitazone. However, GLAXO provided only preliminary results of the analysis to the FDA in September, 2005. The complete results of the study were not provided to the FDA for another year.

4.05 During the following year of concealment, GLAXO pressed its sales of Avandia to a distribution of approximately 13 (thirteen) million prescriptions in the United States. With a month's supply of Rosiglitazone costing between \$90 and \$200, GLAXO was able to rack up sales of \$2.2 billion in 2006 even though it was finally compelled to disclose the complete study results to the FDA in August 2006.

4.06 GLAXO continued onward and upward with its sale of Rosiglitazone after August 2006. Knowing that its drug was unreasonably dangerous and that the diabetic patient population was uninformed of the dangers, GLAXO continued to expand sales of Rosiglitazone to existing and new patients.

4.07 Then on the very same day of May 21, 2007, two (2) significant events took place affecting the parties to this lawsuit. On that day Dr. Steven Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the New England Journal of Medicine with his analysis of the 42 studies which GLAXO had known of since at least September, 2005. Dr. Nissen's study, at last, revealed the

increased risk of heart attack by patients taking Rosiglitazone. The results of Dr. Nissen's study were being revealed to the world on May 21, 2007.

4.08 Braulio Sepulveda died on April 12, 2007, as a result of heart disease which occurred while he was taking Rosiglitazone. While a resident of El Paso County, Texas, Braulio Sepulveda was initially prescribed Rosiglitazone in the form of Avandamet by his treating physician beginning in or around February 2006. Mr. Sepulveda continued to contribute to GLAXO's net profits throughout its banner sales year of 2006 and into 2007 until his heart attack and death.

V. ALLEGATIONS

5.01. Defendant GLAXO negligently, recklessly and wantonly failed to warn Plaintiffs and the general public of the risks associated with taking Rosiglitazone. Defendant GLAXO failed to do so even after various studies have shown that there were problems concerning the cardiovascular safety profile of Rosiglitazone.

5.02. Defendant GLAXO endeavored to deceive Plaintiffs and the general public, by not disclosing its knowledge of the various studies that had shown that there were problems concerning the cardiovascular safety profile of Rosiglitazone.

5.03. Further, Defendant GLAXO did not provide sufficient warnings and instructions that would have put Plaintiff and the general public, on notice of the dangers and adverse effects caused by ingesting Rosiglitazone, including without limitation to risk of heart attack.

5.04. GLAXO designed, manufactured, distributed, sold and/or supplied into the stream of commerce Rosiglitazone in a defective and unreasonably dangerous

condition, as designed, taking into consideration the utility of the drug and the risk to Plaintiff and the general public.

5.05. Rosiglitazone as designed, manufactured, distributed, sold and/or supplied by Defendant GLAXO, was defective as marketed due to inadequate warnings, instructions and/or labeling.

5.06. Rosiglitazone, as designed, manufactured, distributed, sold and/or supplied by Defendant GLAXO, was defective due to inadequate testing before and after Defendant GLAXO's knowledge of the various studies evidencing substantial concerns about the cardiovascular safety profile of Rosiglitazone.

VI. STRICT PRODUCTS LIABILITY

6.01. Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

6.02 Rosiglitazone, as designed, manufactured, sold and/or supplied by Defendant GLAXO, was placed into the stream of commerce by Defendant GLAXO in a defective and unreasonably dangerous condition taking into consideration the utility of the product and the risks involved with the drug's use.

6.03 Further, Rosiglitazone, as designed, manufactured, distributed, sold and/or supplied by Defendant GLAXO, was defective in marketing due to inadequate warnings, instructions, and/or labeling.

6.04 Rosiglitazone, as designed, manufactured, distributed, sold and/or supplied by Defendant GLAXO, was defective due to inadequate testing.

VII. DESIGN AND MARKETING DEFECT

7.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

7.02 Rosiglitazone was defective in design and/or formulation in that, when it left the hands of Defendant GLAXO and/or its representatives, the foreseeable risks of serious harm posed by this drug was sufficiently great in relation to its alleged benefits. The foreseeable risks of serious harm were so much so that Plaintiffs and the general public, having known of such foreseeable risks and alleged benefits, would not have ingested Rosiglitazone.

7.03 Rosiglitazone was also defective due to, not only inadequate warnings and misrepresentations to the general public, but also, inadequate warnings and misrepresentations to healthcare professionals. Defendant GLAXO knew that had healthcare professionals been adequately warned of the serious risks of injury to their patients, healthcare professionals would not have prescribed Rosiglitazone to said patients.

7.04 Rosiglitazone was defective due to inadequate testing before Defendant GLAXO became aware of the risks of ingesting the drug and after Defendant GLAXO became aware of the risks of ingesting the drug.

7.05 As the producing and direct cause and legal result of (i) the design defect of the Rosiglitazone drug; (ii) the marketing defect of the Rosiglitazone drug due to the Defendant GLAXO's failure to adequately warn consumers; and (iii) the defective condition of the Rosiglitazone drug as manufactured and supplied by Defendant

GLAXO and its representatives, Plaintiffs have suffered injuries and monetary damages.

VIII. INADEQUATE AND IMPROPER WARNINGS

8.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and allege:

8.02 Defendant GLAXO was the manufacturer, developer and/or supplier of Rosiglitazone. Rosiglitazone, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the risk of developing serious coronary heart disease after ingesting the drug. Further, Defendant GLAXO failed to warn of these serious risks after Defendant GLAXO had knowledge of same. The information provided to consumers did not reflect Defendant GLAXO's knowledge that Rosiglitazone was not safe and effective as indicated in its aggressive marketing campaign. Nor were consumers made aware that ingesting the drug could result in serious injury, pain and discomfort and/or death. Full and proper warnings that accurately and truthfully reflected the risks of serious injury and/or sudden death due to the ingestion of Defendant GLAXO's Rosiglitazone should have been disclosed with respect this drug.

8.03 As the producing cause and legal and direct result of the failure to warn consumers of the defective condition of Rosiglitazone, as manufactured and/or supplied by Defendant GLAXO and it's representatives, Plaintiffs have suffered injuries and monetary damages.

IX. FRAUD

9.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

9.02 Defendant GLAXO fraudulently represented to the general public, as well as healthcare professionals, that Rosiglitazone was a safe and effective drug. Defendant GLAXO made this representation while knowing that, if healthcare professionals and consumers knew of the serious risks associated with the ingestion of the Rosiglitazone, they would not prescribe and/or ingest this drug. Defendant GLAXO knew its representations to be false, and Plaintiff relied on Defendant GLAXO's false representations in his ingestion of Rosiglitazone. These fraudulent representations by Defendant GLAXO were a proximate cause of the injuries to and monetary losses of Plaintiffs.

X. NEGLIGENCE

10.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

10.02 Defendant GLAXO and its representatives were merchants or sellers of Rosiglitazone. Defendant GLAXO had a duty to exercise reasonable care in the design, manufacturing, marketing, sale, testing and/or distribution of this drug into the stream of commerce. Defendant GLAXO failed to exercise ordinary care in the design, manufacturing, marketing, sale, testing, and/or distribution of the Rosiglitazone drug into interstate commerce. GLAXO knew, or should have known, that its Rosiglitazone

drug greatly increased Plaintiffs' risks of having a heart attack and/or other negative cardiovascular consequences, or of causing sudden cardiac death.

10.03 Despite the fact that Defendant GLAXO knew, or should have known that Rosiglitazone could cause the injuries and/or risk of death, it continued to market, distribute, and sell Rosiglitazone to the public.

10.04 GLAXO knew, or should have known that consumers, such as Plaintiff, would foreseeably suffer such injuries and/or risk of death as a result of GLAXO's failure to exercise ordinary care as described above. Moreover, when Defendant GLAXO became aware of the serious risks of ingesting Rosiglitazone, it owed a legal duty to Plaintiffs, and the general public, to disclose that knowledge. Defendant GLAXO's breach of duty to disclose this information was a proximate cause of the injuries to Plaintiffs.

XI. NEGLIGENT MISREPRESENTATIONS

11.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

11.02 Defendant GLAXO represented and marketed the Rosiglitazone drug as being safe and effective. After Defendant GLAXO became aware of the risk of ingesting Rosiglitazone, however, Defendant GLAXO failed to communicate to Plaintiff and/or the general public, that the ingestion of this drug could cause a person to have a heart attack and/or stroke, or that Rosiglitazone could cause serious coronary heart disease and/or the risk of death to the person ingesting the drug.

11.03. Therefore, Plaintiffs bring this cause of action against Defendant GLAXO under the theory of negligent misrepresentation for the following reasons:

- a) Plaintiffs incorporate all facts and allegations previously stated in this Complaint;
- b) Defendant GLAXO failed to warn Plaintiffs, and other consumers, of the defective condition of the Rosiglitazone, as manufactured and/or supplied by the Defendant GLAXO;
- c) Defendant GLAXO, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Rosiglitazone in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendant GLAXO made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
- d) the above misrepresentations were made to Plaintiffs, as well as the general public;
- e) Plaintiffs and their healthcare providers justifiably relied on Defendant GLAXO's misrepresentations; and
- f) Consequently, Decedent Braulio Sepulveda's ingestion of Rosiglitazone was to his detriment and to the detriment of each of

the Plaintiffs. Defendant GLAXO's negligent misrepresentations proximately caused Plaintiffs' injuries and monetary losses.

XII. EXPRESSED WARRANTY FOR GOODS

12.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

12.02 Defendant GLAXO breached its express warranty of goods. Defendant GLAXO was a merchant and/or seller of Rosiglitazone. Defendant GLAXO sold this drug to consumers for the ordinary purpose for which such drugs are used by consumers. Defendant GLAXO owed a legal duty to Plaintiffs and the public in general to disclose its knowledge of the serious risks of ingesting Rosiglitazone as marketed. This breach of duty by Defendant GLAXO was a proximate cause of the injuries and monetary loss to Plaintiffs.

XIII. WARRANTY OF MERCHANTABILITY

13.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

13.02 Defendant GLAXO breached its implied warrant of merchantability. Defendant GLAXO was a merchant and/or seller of Rosiglitazone. Defendant GLAXO sold this drug to Plaintiffs and other consumers, for the ordinary purpose for which such drug is used by consumers. Rosiglitazone was defective, or unmerchantable, i.e., not fit for the ordinary purposes for which such drugs are used. A defect or defects in the use of this drug for its ordinary purposes caused injuries and monetary losses to Plaintiffs.

XIV. WARRANTY OF FITNESS

14.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein, and further allege:

14.02 Defendant GLAXO breached its implied warranty of fitness. Defendant GLAXO sold Rosiglitazone and, at the time of the sale of this drug, Defendant GLAXO knew or had reason to know of a particular purpose for which the drug was to be used. At the time of the sale of the drug to Braulio Sepulveda, deceased, Defendant GLAXO knew, or had reason to know, that Plaintiffs were relying on the skill and judgment of Defendant GLAXO to select or find a suitable product for the intended purpose. At the time of sale of the drug to Plaintiff, Defendant GLAXO exercised its skill and judgment in the selection of this drug as safe and effective, and Plaintiffs relied thereon. Rosiglitazone was not reasonably fit and/or suitable for the use for which it was selected. Failure of Defendant GLAXO to select and sell a product which was reasonably safe for its intended use proximately caused the injuries and monetary losses to Plaintiffs.

XV. UNJUST ENRICHMENT

15.01 Plaintiffs incorporate by reference all other paragraphs of this Complaint as fully set forth herein, and further allege:

15.02 As a result of GLAXO's materially false and misleading statements and failure to disclose the truth concerning Rosiglitazone defects and dangers, GLAXO has profited and benefited from the sale of Rosiglitazone. Defendant was unjustly enriched

in that Rosiglitazone did not perform as represented to Plaintiff, in fact representing a greater health risk than other diabetes treatments.

15.03 By purchasing Rosiglitazone in ignorance of its undisclosed dangers, Plaintiff has conferred a substantial monetary benefit upon GLAXO, thereby unjustly increasing its wealth.

15.04 GLAXO has benefited and been unjustly enriched by the above alleged conduct. GLAXO has sold, and continues to sell, Rosiglitazone in its defective state, thereby reaping benefits and profits from consumers.

15.05 Defendant GLAXO should be required to disgorge this unjust enrichment.

XVI. WRONGFUL DEATH

16.01 Defendant is liable to the Plaintiffs for the wrongful death of Braulio Sepulveda, Deceased, because the injury that led to his death was caused by the Defendant or its agents' or servants' wrongful acts, neglect, carelessness, unskillfulness, and/or default. TEX PRAC. & REM. CODE § 71 002(b).

XVII. PUNITIVE DAMAGES

17.01 At all times relevant hereto, Defendant GLAXO actually knew of the defective nature of Rosiglitazone as set forth herein and continued to design, manufacture, market, distribute and sell Rosiglitazone so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard of the foreseeable serious harm caused by Rosiglitazone. Defendant GLAXO's deceptive conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, malice, recklessness, and/or willful and intentional disregard for the

safety and rights of Plaintiffs, as well as the general public and/or consumers of Rosiglitazone. Plaintiffs, therefore, are entitled to punitive damages for such conduct.

XVIII. JURY DAMAND

18.01 Plaintiffs hereby request a trial by jury on all issues in this case.

XIX. PRAYER FOR RELIEF

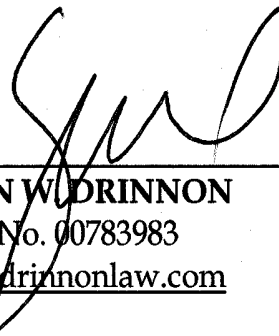
19.01 Plaintiffs pray that a judgment be entered in favor of Plaintiffs in such aggregate sum as will fairly and reasonably compensate Plaintiffs for damages arising out of Defendant's conduct as described herein. The conduct of Defendant, as alleged herein, was a direct, proximate and producing cause of the damages to Plaintiffs and Plaintiffs' Decedent and the following general and specific damages:

- (A) Damages to punish Defendant for proximately causing Plaintiffs' and Decedent's injuries;
- (B) Reasonable attorneys' fees and costs;
- (C) Compensatory, punitive and exemplary damages;
- (D) Physical pain and suffering of Plaintiffs' Decedent;
- (E) Mental anguish of Plaintiffs;
- (F) Medical and Counseling expenses;
- (G) Loss of Companionship and Society of Decedent;
- (H) Funeral Expenses;
- (I) Pre and post-judgment interest at the lawful rate; and /or
- (J) Such other applicable damage as the Court deems appropriate at law or in equity.

Plaintiffs bring this suit within two (2) years of the date of death and of discovering his Avandia related conditions or the existence of any Avandia causes of action.

Respectfully submitted,

THE DRINNON LAW FIRM, P.L.L.C.



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